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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,391	11/12/2003	Gerald B. Pier	B0801.70256US01	8225
7590 08/09/2007				
Maria A. Trevisan Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210				
			EXAMINER	
			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	
			MAIL DATE	DELIVERY MODE
			08/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,391	PIER ET AL.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10, 34, 40, 42, 49, 53, 63, 69-71, 73, 84, 90, 107, 116 and 134-140 is/are pending in the application.
- 4a) Of the above claim(s) 1, 10, 34, 42, 49, 53, 73, 84, 90, 107, 116, 134, 135 and 139 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 63, 69-71, 136-138, and 140 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1, 10, 34, 40, 42, 49, 53, 63, 69-71, 73, 84, 90, 107, 116, 134-140 are pending in the application. Claims 1, 10, 34, 42, 49, 53, 73, 84, 90, 107 and 116 have been previously withdrawn from consideration as drawn to a non-election invention.
2. Newly submitted claims 134, 135, 139 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: SEQ ID NO: 1 is patentably distinct from the elected sequence of SEQ ID NO: 2 contained within the elected Group VII. A search of all the sequences in the patent literature and the non-patent literature cannot be made without serious burden because the sequences require separate searches that have different limits, boundaries, scope, and subject matter.
Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1, 10, 34, 42, 49, 53, 73, 84, 90, 107, 116, 134, 135, 139 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
3. Claims 63, 69-71, 136-138, and 140 are under consideration in this Office Action.
4. The objection to the title of the invention as not being descriptive has been withdrawn in view of applicant's amendment to the title in the amendment dated 05/24/2007.
5. The rejection of claims 63, 69, and 70 under 35 U.S.C. 102(b) as being anticipated by Pier et al. (Accession AAZ87998. 31-MAY-2000; and WO 00/03745. 27 January 2000) has been withdrawn in view of applicants' arguments and amendment to the claims filed 05/24/2007.
6. The rejection of claim 71 under 35 U.S.C. 102(b) as being anticipated by Cramton et al. (Accession AF086783. 01-OCT-1999) has been withdrawn in view of applicants' amendment to the claims filed 05/24/2007.
7. The rejection of claims 63 and 69-71 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicants' arguments and amendment to the claims filed 05/24/2007.

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Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claims 63, 69-71, 136-138, and 140 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claims 63 and 71 are vague and indefinite for reciting the phrase “*ica* locus” and “*ica* nucleic acid” because the specific nucleotide sequence and structure and the encoded proteins and/or enzymes and their identities have not been defined and recited in the claim. It is unclear as to what specific enzyme and/or proteins are enhanced that result in the overproduction of any polysaccharides. Dependent claims 69-70, 136-138, and 140 are also rejected because they do not correct the defect.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
11. Claims 63, 69-71, 136-138, and 140 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The arguments and amendments filed 05/24/2007 have been fully considered but are not persuasive for reasons of record as supplemented below.
The nature and breadth of the claims encompass nucleic acid molecules which when operably linked to an “*ica* nucleic acid” enhances production of any polysaccharide from any coding region of an “*ica* locus” relative to the level produced from a wild-type bacterium.
The specification provides guidance and working examples for the nucleotide sequence of SEQ ID NO: 2. However, the specification does not provide guidance, prediction, and working examples for making and/or using the claimed nucleic acid molecules. The claims recite the

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phrase “*ica* locus” and “*ica* nucleic acid”, but do not recite the specific enzyme and/or proteins involved in polysaccharide production and the specific polysaccharide that is overproduced when the claimed nucleic acid molecule is operably linked to *ica* nucleic acid” It is unclear as to what specific enzyme and/or proteins are enhanced that result in the overproduction of any polysaccharides.

Thus, an undue amount of trial and error experimentation must be performed where such experimentation involves searching and screening for specific enzymes and/or proteins coded by polynucleotides within the “*ica* locus”, making any “*ica* nucleic acid”, operably linking the recited nucleic acid molecule, and determining whether any polysaccharide is overproduced compared to the level of polysaccharide produced from a wild-type bacterium.

The examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific enzyme and/or proteins involved in overproduction of a specific polysaccharide when the recited nucleic acid molecule is operably linked to a specific nucleic acid. Without such a guidance, the amount of experimentation left to those skilled in the art to make and/or use the invention is undue and well outside of routine experimentation.

Conclusion

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday- Friday from 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ponnathapura N. Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization

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where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000. CLF



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